UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YI HU, BORIS NEPOMNICHY and D. WADE WALKE

Application No. 10/041,770

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ORDER UNDER 37 CFR § 41.50(d)

Before WILLIAM F. SMITH, ADAMS and GRIMES, <u>Administrative Patent Judges</u>.

GRIMES, <u>Administrative Patent Judge</u>.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d), we require Appellants to address the following matters:

We invite attention to commonly assigned Application No. 09/564,557.² That application was the subject of an appeal to this board (Appeal No. 2004-0343), which

¹ "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

² The named inventors in the instant application are Yi Hu, Boris Nepomnichy, and D. Wade Walke. In Application No. 09/564,557, the inventors are C. Alexander Turner Jr., Andrew Olson, Brian Zambrowicz, Glenn A. Friedrich, and Arthur T. Sands.

was decided on April 14, 2004. The issues and arguments in Appeal No. 2004-0343 bear close resemblance to those in this appeal. In Appeal No. 2004-0343, the broadest independent claim (claim 1) was directed to "[a]n isolated nucleic acid comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2." The polypeptide of SEQ ID NO:2 was disclosed to have sequence similarity to ion channel proteins, but the specification did not disclose the biological function of the putative ion channel. The only issue in Appeal No. 2004-0343 was whether the specification disclosed a patentable utility for the claimed invention.

In Appeal No. 2004-0343, the appellants argued, among other things, that the claimed nucleic acids had utility because they could be used in methods that do not depend on the biological activity of the encoded protein. The appellants argued that "the present nucleotide sequence has a <u>specific</u> utility in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding areas," and that the claimed nucleic acids "can be used to map exon splice junctions or to 'localiz[e] the specific region of human chromosome 5 that contains the gene encoding the given polynucleotide." Application No. 09/564,557, Paper No. 25, page 16.

The appellants in Appeal No. 2004-0343 also argued that the claimed nucleic acids could be used in "gene chips" or "DNA chips" to monitor gene expression. The appellants argued that "[s]uch 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of DNA chips, such as the presently claimed nucleotide sequence, must also be useful." Id., pages 16-17.

Additionally, the appellants argued that the examiner's position in that case amounted to requiring a unique utility to satisfy § 101, rather than simply a specific utility. The appellants argued that "just because other cDNA sequences can be used to track gene expression does <u>not</u> mean that the present sequences <u>lack</u> a specific utility." <u>ld.</u>, page 20.

The panel that decided Appeal No. 2004-0343 reviewed governing principles of law; addressed and rejected the appellants' arguments premised on DNA chips, gene mapping, and exon splice junctions; and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 27. Accordingly, the examiner's decision, rejecting all of the pending claims in Application No. 09/564,557, was affirmed.

Like the claims in Application No. 09/564,557, in this appeal the broadest independent claim (claim 3) is directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence described in SEQ ID NO:2." According to the specification, the amino acid sequence of SEQ ID NO:2 "share[s] sequence similarity with mammalian proteases." Page 1. The only issue in this appeal is whether the specification discloses a patentable utility for the claimed invention. Examiner's Answer, page 3.

The Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-0343. For example, Appellants argue that:

• "Expression profiling does not require a knowledge of the function of the

particular nucleic acid on the chip" (Appeal Brief, page 7);

- "[T]he described sequences are useful for functionally defining exon splice-junctions" (id., page 6);
- "[T]he present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 1 that contains the gene encoding the given polynucleotide. . . . The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome." (id., page 5);
- "[T]he present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. Such 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful" (<u>id.</u>, page 7);
- "[T]he Examiner seems to be confusing the requirements of a <u>specific</u> utility with a <u>unique</u> utility" (<u>id.</u>, page 6).

On these facts, we require Appellants to explain why we should again address the same line of argument in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-0343, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion than that reached by the panel in Appeal No. 2004-0343, which rejected the same arguments? We note in passing that, according to PTO records, the appellants in Appeal No. 2004-0343 (Application No. 09/564,557) did not request rehearing under 37 CFR § 1.197(b) (now 37 CFR § 41.52), nor did they appeal the Board's decision.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised

in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2004-0343. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response.

This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

William Fismith

Administrative Patent Judge

BOARD OF PATENT

Donald E. Adams

Administrative Patent Judge

APPEALS AND

INTERFERENCES

Eric Grimes

Administrative Patent Judge

Appeal No. 2004-2383 Application No. 10/041,770

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